

Appl. No.: 10/688,712
Amendment dated September 15, 2005
Responsive to Office Action of May 19, 2005

REMARKS

In response to the Office Action mailed May 19, 2005, Applicant respectfully requests the Examiner to reconsider the above-captioned application. By way of this Amendment, Applicant has amended the claims to clarify distinguishing features of the claimed invention. No new matter is added by this Amendment.

Rejection of Claims 11-13 under 35 U.S.C. § 112

The Examiner rejects claims 11-13 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Examiner asserts that there is no nexus between the "radiopaque target" of claim 10 and each of the "markers," "wires," and "basket" in claims 11-13.

In response to the Examiner's rejections, Applicant has amended the claims 11-13 to clarify the nexus between the radiopaque target of claim 10 and the "markers," "wires," and "basket." Applicant wishes to thank the Examiner for noting the indefinite claim language.

Rejection of Claims 1-4 and 21 under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-4 and 21 under 35 U.S.C. §102(b) as being anticipated by St. Goar et al. (U.S. Patent No. 6,629,534). The Examiner asserts that St. Goar et al. disclose a method for determining the axis of a valve, including coaption axis, comprising the steps of: positioning a device within the valve, the device moveable in response to opening and closing of the valve; and observing the device when the valve is closed, to determine the orientation of the coaption axis.

St. Goar et al. disclose methods for assisting in the orientation of medical devices with respect to heart valves. For example, St. Goar et al. disclose an orientation element (element 620) that is used as a reference to determine the location of the valve leaflets before treating the valve. However, St. Goar et al. fail to teach or suggest a method of obtaining information

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regarding the functionality of a valve. In fact, the methods disclosed by St. Goar et al. are not capable of providing information regarding valve functionality.

To further clarify preferred features of Applicant's claimed invention, independent claim 1 has been amended to now recite a method of assessing the functionality of a heart valve, comprising the steps of: 1) positioning a device within the valve, the device being conformable for conforming to the coaption axis of the valve and moveable in response to opening and closing of the valve; and 2) observing the device when the valve is closed, to determine the spatial orientation of the coaptation axis for evaluating valve function. As discussed above, St. Goar et al. fail to disclose a method of assessing functionality of a valve. Rather, St. Goar et al. merely disclose an orientation element (e.g., an inflatable bladder) that is inserted into the valve to determine orientation of the valve. The orientation element is configured such that the valve leaflets may seal against the bladder in systole. (See Col. 20, lines 39-51 of St. Goar et al.) However, the device disclosed by St. Goar et al. does not conform to the coaption axis and is not moveable in response to opening and closing of the valve. Accordingly, St. Goar et al. fail to teach or suggest anything about determining the spatial orientation of the coaption axis for evaluating valve function.

Applicant has also amended independent claim 21 to now recite: A method of assessing the functionality of a valve, comprising the steps of: 1) providing a conformable target, the conformable target having a primary axis and configured to conform to the coaption axis of the valve during opening and closing of the valve; 2) positioning the conformable target within the valve; 3) visualizing the target along a viewing axis which is transverse to the primary axis, in the vicinity of the valve, and 4) observing the orientation of the target when the valve is open and closed for assessing the functionality of the valve. For the same reasons discussed above, St. Goar et al. fail to disclose the method recited in amended claim 21.

In summary, St. Goar et al. fail to anticipate Applicant's independent claims 1 and 21. Therefore, it follows that St. Goar et al. also fail to anticipate dependent claims 2-4. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections of claims 1-4 and 21 under 35 U.S.C. §102(b) based on St. Goar et al.

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It appears that dependent claims 22 and 23 were not examined in the present Office action. With respect to these claims, Applicant notes that dependent claim 22 further recites the step of positioning an implant within the coronary sinus. Dependent claim 23 recites the method of claim 22, wherein the implant is positioned to apply pressure on a posterior leaflet of the mitral valve. Because claims 22 and 23 depend on claim 1 (which is believed to be allowable) and because St. Goar et al. fail to disclose anything about positioning an implant in the coronary sinus, it is believed that dependent claims 22 and 23 are also in condition for allowance.

Rejection of Claims 10-12 under 35 U.S.C. § 102(b)

The Examiner rejects claims 10-12 under 35 U.S.C. §102(b) as being anticipated by Shennib et al. (U.S. Publication No. 2003/0120341). The Examiner asserts that Shennib et al. disclose a method for determining the coaption axis of the mitral valve, comprising the steps of: advancing the distal end of a catheter through the left ventricle to a position adjacent the mitral valve; deploying a radiopaque target from the distal end; and observing the alignment of the radiopaque target in response to closing of the mitral valve.

Shennib et al. disclose devices and methods for securing leaflets of a cardiac valve together. Shennib et al. merely disclose that a leaflet fastener (or clip) may be provided with one or more radiopaque markers. To clarify preferred features of Applicant's claimed invention, independent claim 10 has been amended to recite a method of determining leaflet orientation of a mitral valve which includes the step of deploying a radiopaque target from the distal end of the catheter to a location within the mitral valve, wherein the radiopaque target is sufficiently conformable to reconfigure in response to opening and closing of the mitral valve. Shennib et al. fail to teach or suggest the method recited in Applicant's amended claim 10. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections of claims 10-12 under 35 U.S.C. §102(b) based on Shennib et al.

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Allowable Subject Matter

Applicant appreciates the Examiner's determination that claim 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. §112, second paragraph, set forth in this Office action.

Petition for Extension of Time to Respond

Pursuant to 37 C.F.R. 1.136(a), Applicant hereby requests an extension of time for **One Month** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$120.00 to Deposit Account No. 50-1225 (Docket No. PVI-5809).

CONCLUSION

In light of the foregoing amendments and the above remarks, Applicant presents this application in condition for allowance, and such action is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the attorney of record at the telephone number indicated below.

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Respectfully submitted,



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